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10/590,219	01/17/2007	Mitsuru Emi	295017US0X PCT	6918

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EXAMINER	
REDDIG, PETER J	

ART UNIT	PAPER NUMBER
1642	

NOTIFICATION DATE	DELIVERY MODE
09/02/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/590,219	EMI ET AL.	
	Examiner	Art Unit	
	PETER J. REDDIG	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *1-4,6-9 and 13-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5, 10-12, and 17-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/22/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Election filed July 23, 2009 in response to the Office Action of June 24, 2009 is acknowledged and has been entered. Applicant's election with traverse of Group 5, claims 5, 10-12 and 17-19, in part, and the species AI066764/lectin, galactoside-binding, soluble, 1 (galectin-1) is acknowledged.

Applicants argue that restriction is only proper if the claims of the restricted groups are independent or patentably distinct and there would be a serious burden placed on the Office if restriction is not required (MPEP §803). The burden is on the Office to provide reasons and/or examples to support any conclusion in regard to patentable distinction (MPEP § 803). Moreover, when citing lack of unity of invention in a national stage application, the Office has the burden of explaining why each group lacks unity with the others (MPEP § 1893.03(d)), i.e. why a single general inventive concept is nonexistent. The lack of a single inventive concept must be specifically described.

Applicants argue that the Office alleges that Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

> The technical feature linking Groups 1-10 appears to be a gene selected from the following sequences correlated with the prediction of the postoperative prognosis of primary breast cancer. However, Chu et al. (Journal of Biological Chemistry, Vol. 260, No. 7, pages 4357-4363, 1985, IDS) teach pro-alpha-1 type 3 collagen, see abstract, p. 4357. Therefore, the technical feature linking the inventions of Groups 1-10 does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art.

Applicants argue that Annex B of the Administrative Instructions under the PCT, paragraph b (Technical Relationship), states, emphasis added:

> The expression "special technical feature" is defined in Rule 13.2 as meaning those technical features that defines a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any).

Applicants argue that the Office did not consider the contribution of each invention, as a whole, in alleging the lack of a special technical feature. Applicants also respectfully submit that the Office has not provided any indication that the contents of the claims interpreted in light of the description were considered in making this allegation. Therefore, the Office has not met the burden necessary to support the assertion of a lack of unity of the invention.

Applicants' arguments have been considered, but have not been found persuasive. The specification teaches the invention is drawn to a gene correlated with prediction of the postoperative prognosis of breast cancer (see page 1) and claims are drawn to different sets of a gene correlated with prediction of the postoperative prognosis of breast cancer. Thus, given that Chu et al. teach a claimed gene, pro-alpha-1 type 3 collagen, and intended uses do not distinguish the gene from the prior art and given the claims are drawn to a gene from multiple, different genes, the finding of lacking of unity is proper furthermore. Furthermore burden of search is not the criteria for proper restriction under PCT article 17(3)(a) and 1.476 (c), 37 CFR 1.475(d).

Applicants argue that in regard to the election of species requirement, the Office alleges that "[t]he species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicants make no statement regarding the patentable distinctness of the species, but note that for restriction to be proper, there must be a patentable difference between the species as claimed. MPEP § 808.01(a). The Office has not provided any reasons or examples to support a conclusion that the species, as claimed, are indeed patentably distinct. Accordingly, Applicants respectfully submit that the restriction is improper, and Applicants' election of species is for examination purposes only.

Applicants argue that the Office has failed to meet the burden necessary in order to sustain the requirement for restriction. Applicants therefore request that the requirement for restriction be withdrawn.

Applicants' arguments have been considered, but have not been found persuasive. Given that the lack of unit of invention is proper for the reasons set forth above and given that that multiple claimed genes are structurally and functionally distinct molecules that are mutually exclusive that would required distinct search and examination, the requirement for an election of species is proper. For the reasons previously set forth and above the restriction requirement is deemed to be proper and is therefore made FINAL.

2. Claims 1-19 are pending.

3. Claims 1-4, 6-9, 13-16 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.

4. Claims 5, 10-12, and 17-19 drawn to the species AI066764/lectin, galactoside-binding, soluble, 1 (galectin-1) are currently under consideration.

Priority

5. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

It is noted that examiner has established a priority date for claims 5, 10-12, and 17-19 of the instant application, 10/590,219, of August 24, 2004 because the priority of the instantly claimed invention is based on the Japanese application 2004-048593, which has not been translated and the Examiner is unable to determine the information in the document.

If applicant disagrees with any rejection set forth in this action based on examiner's establishment of a priority date of August 24, 2004, Applicants are invited to submit a proper translation of the priority document and to point to page and line where support can be found establishing an earlier priority date. If Applicants choose to file a translation, then the translation must be filed together with a statement that the translation of the certified copy is accurate, see MPEP 201.15.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 5 and 10 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 5 and 10 as written, do not sufficiently distinguish over an AI066764/lectin, galactoside-binding, soluble, 1 (galectin 1) gene as it exists naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). In order to obviate the instant

rejection, the Examiner suggests that the claims should be amended to indicate the hand of the inventor, e.g., by insertion of "isolated" or "purified" provided the support for such an amendment can be identified in the specification as originally filed. See MPEP 2105.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 5, 10-12, and 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite in the use of in the use of the designations "AI066764" as a means of identifying the gene. The use of accession numbers does not satisfy the requirements of 35 USC 112, second paragraph because accession numbers and the sequences corresponding to accession numbers are not unique identifiers required for genes/nucleic acid sequences because they can be modified, changed, and/or updated, and thus the cited sequence may vary or change over time. Thus, identifying a molecule by accession number does not provide a reliable unique identifier. Amendment of the claims to refer solely to galectin-1 would obviate this rejection.

Additionally, the parentheses around "node negative" in claim 5 render the claim indefinite because it is unclear whether the parenthetical limitations are part of the claimed invention. Removal of the parentheses around "node negative" would obviate this rejection.

Furthermore, as drawn to claims 17-19 the term "a reagent using as a marker the gene and/or probe. . . " is indefinite as it unclear how the reagent is using the gene and/or probe.

Amendment of the claim to a "a reagent comprising a marker the gene and/or probe. . ." would obviate this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 5 and 10-12 are rejected under 35 U.S.C. 102(a) as being anticipated by Nagahata et al. (Cancer Sci., March 2004, 95: 218-225, IDS).

It is noted that the recitation of "gene selected from the following sequences correlated with prediction of the postoperative prognosis, in (node-negative)(n0) breast cancer with no metastasis to a lymph node" in Claims 5 and 10-12 is merely suggestive of an intended use that does not result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art and thus is not given weight for comparison of the claims with the prior art.

Additionally it is noted that in the absence of a limiting definition of a fiber type microarray, any microarray is a fiber type microarray.

Nagahata et al. teach construction of a cDNA microarray comprising 25,344 cDNAs for the prediction of prediction of postoperative prognosis of estrogen receptor negative breast cancer, see Title, Abstract, and p.219.

Although the reference does not specifically state that the microarray comprised a probe for galectin-1, given that article was co-authored by the three inventors of the instant application prepared with the same method of preparation using the same number of cDNAs (see p. 29-lines 1-5 of the specification and p. 219 of Nagahata et al.) the claimed product appears to be the same as the prior art product, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed method is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977).

9. Claims 5 and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Mackay et al. (Oncogene May 1, 2003 22: 2680-8).

It is noted that the recitation of "gene selected from the following sequences correlated with prediction of the postoperative prognosis, in (node-negative)(n0) breast cancer with no metastasis to a lymph node" in Claims 5 and 10-12 is merely suggestive of an intended use that does not result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art and thus is not given weight for comparison of the claims with the prior art.

Additionally it is noted that in the absence of a limiting definition of a fiber type microarray, any microarray is a fiber type microarray.

Mackay et al. teach a cDNA microarray comprising probes for galectin-1, see Abstract, Table 1, and Materials and Methods.

10. Claims 5 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Soares et al. (GenBank: AI066764.1, ov25h01.x1, August 13, 1998).

It is noted that the recitation of "gene selected from the following sequences correlated with prediction of the postoperative prognosis, in (node-negative)(n0) breast cancer with no metastasis to a lymph node" in Claims 5 and 10 is merely suggestive of an intended use that does not result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art and thus is not given weight for comparison of the claims with the prior art.

Soares et al. teach AI066764.1 which can be a probe for the galectin-1 gene.

11. Claims 5 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Couraud et al. (NM_002305, galectin-1, LGALS1 March 1999).

It is noted that the recitation of "gene selected from the following sequences correlated with prediction of the postoperative prognosis, in (node-negative)(n0) breast cancer with no metastasis to a lymph node" in Claims 5 and 10 is merely suggestive of an intended use that does not result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art and thus is not given weight for comparison of the claims with the prior art.

Couraud et al. teach NM_002305/ galectin-1/ LGALS1 which can be a probe for the galectin-1 gene.

12. Claims 5, 10-12, and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat App. Pub. 2003/0087251 (Kurn May 8, 2003).

It is noted that the recitation of "gene selected from the following sequences correlated with prediction of the postoperative prognosis, in (node-negative)(n0) breast cancer with no metastasis to a lymph node" in Claims 5 and 10-12 and "A diagnosis kit for the postoperative prognosis of breast cancer" is merely suggestive of an intended use that does not result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art and thus is not given weight for comparison of the claims with the prior art.

US Pat App. Pub. 2003/0087251 teach detection of LGALS1 (galectin-1, see Couraud et al.) in human colon tumor RNA by PCR amplification. See Example 5, Fig. 10, and para. 0443. US Pat App. Pub. 2003/0087251 teaches making microarrays and fiber microarrays with probes for the amplification products of the invention, see paras. 0048-0050, 0125, 0242, and 0276 and claims 120 and 128. US Pat App. Pub. 2003/0087251 teaches kits comprising the microarrays of the invention, para. 0074, 00274-0290.

13. No claims allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to PETER J. REDDIG whose telephone number is (571)272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Helms Larry can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Peter J Reddig/
Examiner, Art Unit 1642